

Appl. No. 09/643,686  
Amendment dated December 15, 2004  
Reply to Office Action of June 15, 2004

### Remarks

Entry of the amendment is respectfully requested prior to the issuance of an action of the merits of the application.

Claims 3-19, 22, 24-27 and 28 are pending in the application. Claims 24-26 remain withdrawn from further reconsideration by the Examiner as directed to a non-elected invention. Claim 23 has been canceled. the subject matter of claim 23 has been included in both claims 27 and 28 as amended. Claim 27 has been amended to conform with the addition of the mirror element. Claim 28 has been further amended to more clearly indicate that the placement of the receiver. (Support may be found, for example on page 12 at lines 7-15 and on page 13, at lines 17-21).

The Examiner is thanked for the courtesies extended during the interview held on February 22, 2005. The substance of the interview is accurately set forth in the Interview Summary form provided to the undersigned. The amendment reflects some of the advice provided and the frank discussions at the interview.

The WO 01/14859 A1 Document was brought to the Examiner's attention. The inventors named on this document are the applicants here. The document was published on March 1, 2001. The instant application has priority based on the EP Application filed on August 24, 1999.

### Rejections under 35 U.S.C. § 103

Claims 2-19, 22, and 27 were finally rejected under 35 U.S.C. §103(a) as being unpatentable over Lekkala et al. (WO 95/22754) in view of Babson et al. (U.S. Patent No. 5,885,530). Applicants respectfully traverse.

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Lekkala et al. describes a device and method which relies on a different assay formula than that claimed and disclosed. Lekkala et al. does not appear to describe their vessel as being of one piece construction. See page 6 starting at line 20. Lekkala et al. measures a difference in reflected light due to a resonance phenomenon. Note that the Lekkala et al. "receiving element" (6, 14, 15) is not directly underneath the base and does not appear to be positioned to receive emitted fluorescent rays and/or phosphorescent rays. The resonance phenomenon relied upon by Lekkala et al. amplifies the so-called evanescent electric field, which is generated in the total reflection. An evanescent field, created by a light source, "sees" the reaction taking place on the reaction surface (material layer), e.g. the formation of a complex between the antibody bound on the material layer and the antigen analyte in the sample, because the reaction corresponds to a definite change of the refraction index, due to the formed complex, on the surface of the material layer. The degree of binding can be measured from the reflected light because resonance (disappearance of light) is shifted to another value of incident angle. See page 3 starting at line 26. The measurement based on this SPR phenomenon is conducted from the direction of the bottom of the structure through a suitable prism structure. If one contrasts the figures of the instant application with those of Lekkala et al., e.g. Figures 2a-2c and 4a-b, one can readily see the differences in the measurement mechanism. Lekkala et al. measures the degree of binding due to a loss in the reflected light. The instant invention measures the fluorescence or phosphorescence due to the bound label at an angle distinct from that of the reflect light beam. See, for example, instant Figure 1. This different assay protocol necessitates different positioning of device elements, e.g. receiver (10) relative to those of Lekkala et al.

Babson et al. patent has been reviewed. It is not seen how it remedies the deficiencies of Lekkala et al., noted above. While Babson et al. does teach an automated immunoassay analyzer, this analyzer is not based on either the Lekkala et al. SBR based assay or the sandwich assay device claimed. There is no mention of the SPR or an equivalent phenomenon nor is the Babson et al. device set up to measure light differences like those disclosed by Lekkala et al. Babson et al. employ a traditional heterogeneous immunoassay format. The Babson et al. substrates for the immobilized

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phase are a collection of beads and not the bottom surface of an assay well. The Babson et al. measurement mechanism and device is distinct from that used either for Lekkala et al. SPR based device or that claimed.

The propriety of the reference combination is questioned. It is not seen how or why one would combine the references. There is no apparent problem in either reference for which the other provides a solution. There is not even a similarity in assay format. Lekkala et al. teaches as an advantage the absence of labels. Babson et al. employs labels. Further, the use of labels in Lekkala et al. assay format would necessitate changes in the measuring device. There is no guidance as to how the requisite changes would be made. There is no motivation referred to in the Office Action which would suggest why the changes would be made, even if they were taught.

Further, both the independent claims now include the feature from original claim 23. The light beams are guided from the vessels via a polygonal mirror 22 (as stationary deflection unit) to the receiver. The device as claimed can be used to detect without moving parts a plurality of vessels with light rays, and without the light rays mutually influencing each other which would result in distorting the measuring values.

Please note the with Lekkala et al., several receiving elements must be provided (Figures 4a, b) to detect a plurality of vessels. This results in a widely fanned out beam from the light source and the danger that the light rays in front of the individual vessels cannot be independently detected by the individual receiving elements. In contrast, each vessel of the claimed device can be detected individually, even though only one receiver is used for all vessels.

The measuring principle used for the claimed device differs fundamentally from that of Lekkala et al.

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Also, while Babson et al. describes an arrangement involving several vessels, Babson et al. device employs one transmitter and one receiver. This allows only one vessel to be detected at a time. To detect several vessels using this arrangement, each individual vessel must be separately supplied and measured. The evaluation inherent with the Babson device is considerably more involved and expensive than that claimed. A costly conveying mechanism, which is required by Babson et al. to individually deliver the vessels to the detection station, is avoided. Accordingly, the evaluation associated with the Babson et al. device would be more involved and therefore slower than the claimed device since less steps are required. According to Babson et al., each individual vessel must be delivered separately to the detection device before the measuring for (only one!) vessel can be realized. With the device according to our invention, several vessels can be arranged stationary and can be measured successively without moving any parts, thus resulting in considerably shorter passage times than those according to Babson et al.

It is respectfully requested that the rejection be withdrawn since a proper prima facie case of obviousness has not been established based on the assembled references.

### Conclusion

All of the stated grounds of rejections have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

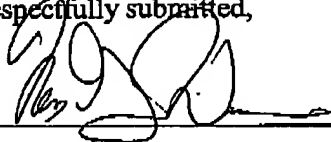
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A Notice of Allowance with claims 2-19, 22, 27 and 28 is respectfully requested.

Date: \_\_\_\_\_

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Respectfully submitted,



Thomas G. Wiseman  
Registration No. 35,046  
VENABLE LLP  
P.O. Box 34385  
Washington, D.C. 20043-9998  
Telephone: (202) 344-4800  
Direct dial: (202) 344-4614  
Telefax: (202) 344-8300

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